



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1002]

Guidance for Industry: Questions and Answers Regarding Food Facility Registration
(Fifth Edition)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Questions and Answers Regarding Food Facility Registration (Fifth Edition).” The guidance provides updated information pertaining to registration of human and animal food facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA) on January 4, 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to the Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels

to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Amy Barringer,
Center for Food Safety and Applied Nutrition (HFS-615),
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740,
240-402-1988.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Questions and Answers Regarding Food Facility Registration (Fifth Edition),” which replaces the fourth edition of a guidance entitled “Questions and Answers Regarding Registration of Food Facilities (Edition 4)” issued in August 2004. The guidance provides updated information pertaining to the registration of food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

On October 10, 2003, FDA issued an interim final rule (68 FR 58894) to implement amendments to the FD&C Act made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107-188). Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. This

guidance was developed to answer frequently asked questions relating to the registration requirements of section 415.

Section 102 of FSMA (Public Law 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act, in relevant part, to require facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States to submit additional registration information to FDA. This revised edition of the guidance includes new information relating to the FSMA amendments to section 415.

The first edition of this document was issued as level 2 guidance under § 10.115 (21 CFR 10.115) and was made available on FDA's Web site on December 4, 2003. The second, third, and fourth editions of this document were issued as level 1 guidance documents under § 10.115 and were made available on FDA's Web site on January 12, 2004, February 17, 2004, and August 2004, respectively. This revision (fifth edition) is being issued as a level 1 guidance and includes questions and answers relating to the FSMA amendments to section 415 of the FD&C Act. In addition, the guidance provides non-substantive revisions to clarify, delete, and renumber the questions and answers in edition 4.

This guidance is being issued consistent with FDA's good guidance practices regulation § 10.115 as a level 1 guidance. The Agency will accept comments at any time, but it is implementing this guidance immediately, in accordance with § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate.

The guidance represents the Agency's current thinking on food facility registration. It does not create or confer any rights for or on any person and does not

operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and section 415 of the FD&C Act. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in §§ 1.230 through 1.235 and section 415 of the FD&C Act have been approved under OMB control number 0910-0502.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: December 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-30328 Filed 12/14/2012 at 8:45 am; Publication Date: 12/17/2012]